

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Solomon Steiner, Robert Feldstein, Huiling Lian, Christopher A. Rhodes, and Gregory S. Shen

Serial No.: Continuation of 10/211,215 Art Unit: Not Yet Assigned

Filed: November 12, 2003 Examiner: Not Yet Assigned

For: *METHOD FOR DRUG DELIVERY TO THE PULMONARY SYSTEM*

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including five (5) pages of Form PTO-1449 and copies of sixteen (16) documents cited therein. All of the documents cited below were cited by or submitted to the Patent Office in Application Serial No. 08/441,378, filed May 15, 1995, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however. Copies of the newly cited documents, which are identified with an asterisk (*), are enclosed.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
3,906,950	09-23-1975	Cocozza	128/266
3,921,637	11-25-1975	Bennie, et al.	128/266
4,272,398	06-09-1981	Jaffe	427/213.31
4,861,627	08-29-1989	Mathiowitz	427/213.31
5,145,684	09-08-1992	Liversidge, et al.	424/489
5,260,306	11-09-1993	Boardman, et al.	424/45
5,352,461	10-04-1994	Feldstein, et al.	424/493
*5,458,135	10-17-1995	Patton, et al.	128/200.14
5,492,112	02-20-1996	Mecikalski, et al.	128/203.15
5,577,497	11-26-1996	Mecikalski, et al.	128/203.15
5,653,961	08-05-1997	McNally, et al.	424/45
*5,658,878	08-19-1997	Bäckström, et al.	514/3
5,740,794	04-21-1998	Smith, et al.	128/203.15
*5,747,445	05-05-1998	Bäckström, et al.	514/4
5,785,049	07-28-1998	Smith, et al.	128/203.15
5,874,064	02-23-1999	Edwards, et al.	424/46
5,901,703	05-11-1999	Ohki, et al.	128/203.12
*5,952,008	09-14-1999	Bäckström, et al.	424/499
*5,997,848	12-07-1999	Patton, et al.	424/46

Foreign Documents

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
0 257 915	02-03-1988	Innovata Biomed Ltd.	EP
*2 240 337	07-31-1991	National Research Development Corporation	GB
*2-149545	02-12-1992	Taisho Pharmaceutical Co.	JP
WO 91/04011	04-04-1991	Riker Laboratories Inc.	PCT
WO 92/08509	05-29-1992	Minnesota Mining and Manufacturing Company	PCT
*WO 93/02712	02-18-1993	Danbiosyst UK Limited	PCT
WO 93/18754	09-30-1993	Pharmaceutical Discovery Corporation	PCT

Publications

BENITA, "Characterization of Drug-Loaded Poly(d,l-lactide) Microspheres," *J. Pharm. Sci.*, 73: 1721-1724 (1984).

*BENSCH, et al., "Absorption of intact protein molecules across the pulmonary air-tissue barrier," *Science* 156: 1204-1206 (1967).

*ELLIOTT, et al., "Parenteral absorption of insulin from the lung in diabetic children," *Austr. Paediatr. J.* 23: 293-297 (1987).

GUPTA, "Contemporary Approaches in Aerosolized Drug Delivery to the Lung," *J. Controlled Release*, 17(2): 127-147 (1991).

*HEYDER, "Alveolar deposition of inhaled particles in humans," *Am. Ind. Hyg. Assoc. J.* 43(11): 864-866 (1982).

KATCHALSKI, "Synthesis of Lysine Anhydride," *J. Amer. Chem. Soc.*, 68: 879-880 (1946).

*KOMADA, et al., "Intratracheal delivery of peptide and protein agents: absorption from solution and dry powder by rat lung," *J. Pharm. Sci.* 83(6): 863-867 (1994).

KOPPLE, "A Convenient Synthesis of 2,5-Piperazinediones," *J. Org. Chem.*, 33(2): 862-864 (1968).

LIM, "Microencapsulation of Living Cells and Tissues," *J. Pharm. Sci.*, 70: 351-354 (1981).

MATHIOWITZ, "Morphology of Polyanhydride Microsphere Delivery Systems," *Scanning Microscopy*, 4: 329-340 (1990).

MATHIOWITZ, "Novel Microcapsules for Delivery Systems," *Reactive Polymers*, 6: 275-283 (1987).

MATHIOWITZ, "Polyanhydride Microspheres As Drug Carriers I. Hot-Melt Microencapsulation," *J. Controlled Release*, 5: 13-22 (1987).

MATHIOWITZ, "Polyanhydride Microspheres as Drug Carriers. II. Microencapsulation by Solvent Removal," *J. Appl. Polymer Sci.*, 35: 755-774 (1988).

MATHIOWITZ, "Polyanhydride Microspheres. IV. Morphology and Characterization of Systems Made by Spray Drying," *J. Appl. Polymer Sci.*, 45: 125-134 (1992).

MOREN, Aerosols in Medicine, (2nd ed.), Elsevier, pp. 321-350.

*OKUMURA, et al., "Intratracheal delivery of insulin. Absorption from solution and aerosol by rat lung," *Int. J. Pharmaceuticals* 88: 63-73 (1992).

*PATTON & PLATZ, "Routes of Delivery: Case Studies. Pulmonary delivery of peptides and proteins for systemic action," *Adv. Drug. Del. Rev.* 8: 179-196 (1992).

U.S.S.N.: Continuation of 10/211,215
Filed: November 12, 2003
INFORMATION DISCLOSURE STATEMENT

SALIB, "Utilization of Sodium Alginate in Drug Microencapsulation," *Pharazeutische Industrie*, 40(11a): 1230-1234 (1978).

SAWHNEY, "Bioerodible Hydrogels Based on Photopolymerized Poly(ethylene glycol)-co-poly(a-hydroxy acid) Diacrylate Macromers," *Macromolecules*, 26: 581-587 (1993).

*WIGLEY, et al., "Insulin across respiratory mucosae by aerosol delivery," *Diabetes* 20(8): 552-556 (1971).

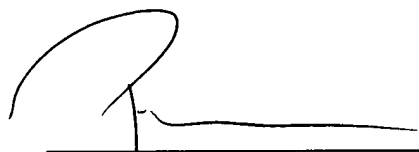
WITCHERT, "Low Molecular Weight PLA: A Suitable Polymer for Pulmonary Administered Microparticles," *J. Microencapsulation*, 10(2): 195-207 (1993).

*YOSHIDA, et al., "Absorption of insulin delivered to rabbit trachea using aerosol dosage form," *J. Pharm. Sci.* 68(5): 670-671 (1979).

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst
Reg. No. 31,284

Dated: November 12, 2003

HOLLAND & KNIGHT LLP
One Atlantic Center
1201 West Peachtree Street, N.E.
Suite 2000
Atlanta, Georgia 30309-3400
404-817-8473
FAX 404-817-8588
www.hklaw.com

1340967_v1



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

<p>Substitute for form 1449A/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(use as many sheets as necessary)</p>			Complete if Known		
			Application Number		Continuation of 10/211,215
			Filing Date		November 12, 2003
			First Named Inventor		Solomon Steiner
			Group Art Unit		
			Examiner Name		
Sheet	1	of	5	Attorney Docket Number	PDT 103 CON (3)

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		3,906,950		Cocozza	09-23-1975	
		3,921,637		Bennie, et al.	11-25-1975	
		4,272,398		Jaffe	06-09-1981	
		4,861,627		Mathiowitz	08-29-1989	
		5,145,684		Liversidge, et al.	09-08-1992	
		5,260,306		Boardman, et al.	11-09-1993	
		5,352,461		Feldstein, et al.	10-04-1994	
		5,458,135		Patton, et al.	10-17-1995	
		5,492,112		Mecikalski, et al.	02-20-1996	
		5,577,497		Mecikalski, et al.	11-26-1996	
		5,653,961		McNally, et al.	08-05-1997	
		5,658,878		Bäckström, et al.	08-19-1997	
		5,740,794		Smith, et al.	04-21-1998	
		5,747,445		Bäckström, et al.	05-05-1998	
		5,785,049		Smith, et al.	07-28-1998	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
		EP	0 257 915		Innovata Biomed Ltd.	02-03-1988		
		GB	2 240 337		National Research Development Corporation	07-31-1991		
		JP	2-149545		Taisho Pharmaceutical Co.	02-12-1992		
		PCT	WO 91/04011		Riker Laboratories Inc.	04-04-1991		
		PCT	WO 92/08509		Minnesota Mining and Manufacturing Company	05-29-1992		
		PCT	WO 93/02712		Danbiosyst UK Limited	02-18-1993		

Examine Signature		Date Considered	
-------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.

Please type a plus sign (+) inside this box →



PTO/SB/08A (10-98)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
		Application Number	
		Continuation of 10/211,215	
		Filing Date	
		November 12, 2003	
		First Named Inventor	
		Solomon Steiner	
Group Art Unit			
Examiner Name			
Sheet	2	of	5
Attorney Docket Number		PDT 103 CON (3)	

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		5,874,064		Edwards, et al.	02-23-1999	
		5,901,703		Ohki, et al.	05-11-1999	
		5,952,008		Bäckström, et al.	09-14-1999	
		5,997,848		Patton, et al.	12-07-1999	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
		PCT	WO 93/18754		Pharmaceutical Discovery Corporation	09-30-1993		

Examine Signature		Date Considered	
-------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.



Please type a plus sign (+) inside this box →



PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

<p>Substitute for form 1449A/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(use as many sheets as necessary)</p>		Complete if Known			
		Application Number	Continuation of 10/211,215		
		Filing Date	November 12, 2003		
		First Named Inventor	Solomon Steiner		
		Group Art Unit			
		Examiner Name			
Sheet	3	of	5	Attorney Docket Number	PDT 103 CON (3)

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		BENITA, "Characterization of Drug-Loaded Poly(d,L-lactide) Microspheres," <i>J. Pharm. Sci.</i> 73: 1721-1724 (1984).	
		BENSCH, et al., "Absorption of intact protein molecules across the pulmonary air-tissue barrier," <i>Science</i> 156: 1204-1206 (1967).	
		ELLIOTT, et al., "Parenteral absorption of insulin from the lung in diabetic children," <i>Austr. Paediatr. J.</i> 23: 293-297 (1987).	
		GUPTA, "Contemporary Approaches in Aerosolized Drug Delivery to the Lung," <i>J. Controlled Release</i> , 17(2): 127-147 (1991).	
		HEYDER, "Alveolar deposition of inhaled particles in humans," <i>Am. Ind. Hyg. Assoc. J.</i> 43(11): 864-866 (1982).	
		KATCHALSKI, "Synthesis of Lysine Anhydride," <i>J. Amer. Chem. Soc.</i> , 68: 879-880 (1946).	
		KOMADA, et al., "Intratracheal delivery of peptide and protein agents: absorption from solution and dry powder by rat lung," <i>J. Pharm. Sci.</i> 83(6): 863-867 (1994).	
		KOPPLE, "A Convenient Synthesis of 2,5-Piperazinediones," <i>J. Org. Chem.</i> , 33(2): 862-864 (1968).	
		LIM, "Microencapsulation of Living Cells and Tissues," <i>J. Pharm. Sci.</i> , 70: 351-354 (1981).	
		MATHIOWITZ, "Morphology of Polyanhydride Microsphere Delivery Systems," <i>Scanning Microscopy</i> , 4: 329-340 (1990).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

<p>Substitute for form 1449A/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(use as many sheets as necessary)</p>		Complete if Known			
		Application Number	Continuation of 10/211,215		
		Filing Date	November 12, 2003		
		First Named Inventor	Solomon Steiner		
		Group Art Unit			
		Examiner Name			
Sheet	4	of	5	Attorney Docket Number	PDT 103 CON (3)

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		MATHIOWITZ, "Novel Microcapsules for Delivery Systems," <i>Reactive Polymers</i> , 6: 275-283 (1987).	
		MATHIOWITZ, "Polyanhydride Microspheres As Drug Carriers I. Hot-Melt Microencapsulation," <i>J. Controlled Release</i> , 5: 13-22 (1987).	
		MATHIOWITZ, "Polyanhydride Microspheres as Drug Carriers. II. Microencapsulation by Solvent Removal," <i>J. Appl. Polymer Sci.</i> , 35: 755-774 (1988).	
		MATHIOWITZ, "Polyanhydride Microspheres. IV. Morphology and Characterization of Systems Made by Spray Drying," <i>J. Appl. Polymer Sci.</i> , 45: 125-134 (1992).	
		MOREN, <i>Aerosols in Medicine</i> , (2nd ed.), Elsevier, pp. 321-350.	
		OKUMURA, et al., "Intratracheal delivery of insulin. Absorption from solution and aerosol by rat lung," <i>Int. J. Pharmaceuticals</i> 88: 63-73 (1992).	
		PATTON & PLATZ, "Routes of Delivery: Case Studies. Pulmonary delivery of peptides and proteins for systemic action," <i>Adv. Drug. Del. Rev.</i> 8: 179-196 (1992).	
		SALIB, "Utilization of Sodium Alginate in Drug Microencapsulation," <i>Pharmazeutische Industrie</i> , 40(11a): 1230-1234 (1978).	
		SAWHNEY, "Bioerodible Hydrogels Based on Photopolymerized Poly(ethylene glycol)-co-poly(a-hydroxy acid) Diacrylate Macromers," <i>Macromolecules</i> , 26: 581-587 (1993).	
		WIGLEY, et al., "Insulin across respiratory mucosae by aerosol delivery," <i>Diabetes</i> 20(8): 552-556 (1971).	

Examiner's Signature	Date Considered
----------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

